SUMMARY OF CHANGES – Consent for use in the Experimental Therapeutics Clinical Trials Network (ETCTN) Biobanking and Molecular Characterization Initiative (BMCI)

NCI Protocol #: 10186
Local Protocol #: 201901009
Protocol Version Date: 01/27/2025
Protocol Title: A Phase I/II Study of Nivolumab plus or minus Ipilimumab in Combination with Multi-fraction Stereotactic Radiosurgery for Recurrent High-grade Radiation-relapsed Meningioma

Informed Consent Version Date: 01/27/2025

#	Section	Change
1.	Header	The only change was updating the protocol and consent version dates

^Notes for Local Investigators:

- The goal of the informed consent process is to provide potential study participants with clear, accurate, unbiased, and sufficient information so that they can make informed choices about participating in research. The ICD is one part of the consent process. It provides a summary of the study, describes foreseeable risks, discusses the individual's rights as a study participant, and documents their willingness to participate. The ICD, however, is only one piece of an ongoing exchange of information between the investigator and study participant.

- Sections that will require edits from local site investigators are highlighted in red. These instructions and formatting should remain in the consent form for the local sites. Local sites should remove them from the consent form for patients.

- Local investigators should be sure to update the imaging risk information in the "What risks can I expect from taking part in this study?" section based on local site dosimetry in accordance with institutional policies and procedures.

These notes for investigators should not be included in the ICD sent to local IRBs.

Research Study Informed Consent Document

Study Title for Participants: Testing Nivolumab (with or without Ipilimumab) with Radiosurgery for Recurrent High-grade Meningioma – Phase II (Treatment A)

Official Study Title for Internet Search on http://www.ClinicalTrials.gov: Protocol 10186 "A Phase I/II Study of Nivolumab plus or minus Ipilimumab in Combination with Multi-fraction Stereotactic Radiosurgery for Recurrent High-grade Radiation-relapsed Meningioma (NCT Pending)

Overview and Key Information

What am I being asked to do?

We are asking you to take part in a research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

We are asking you to take part in this research study because you have an aggressive brain tumor that has returned after radiation therapy.

Taking part in this study is your choice.

You can choose to take part or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document has important information to help you make your choice. Take time to read it. Talk to your doctor, family, or friends about the risks and benefits of taking part in the study. It's important that you have as much information as you need and that all your questions are answered. See the "Where can I get more information?" section for resources for more clinical trials and general cancer information.

Why is this study being done?

This study is being done to see if your recurrent brain tumor may respond to a combination of radiosurgery (a type of radiation therapy) with nivolumab (a type of immunotherapy drug). A small number of patients have already received this combination previously and have tolerated the treatment relatively well. However, we would like to see if the combination treatment may be better or worse than the standard approach of radiosurgery alone. We would also want to learn more about the side effects associated with giving nivolumab with radiosurgery.

We are doing this study because there is currently a lack of effective methods to treat this type of brain tumor that has returned after prior radiation therapy. We want to find out if this approach is

better or worse than the usual approaches that most people get for your type of brain tumor. The usual approach is defined as care most people get for your type of brain tumor.

What is the usual approach to my type of brain tumor?

The usual approach for patients who are not in a study is treatment by repeating radiation therapy such as radiosurgery or chemotherapies that typically have limited effectiveness. There are no treatments that are proven to help patients with your health condition live longer.

What are my choices if I decide not to take part in this study?

- You may choose to have the usual approach described above.
- You may choose to take part in a different research study, if one is available.
- You may choose not to be treated brain tumor.
- You may choose to only get comfort care to help relieve your symptoms and not get treated for your brain tumor.

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will get the study drug nivolumab for up to 12 months along with a type of radiation therapy called stereotactic radiosurgery at the beginning of the study (3 radiation treatments. Stereotactic radiosurgery is a type of radiation therapy that uses precisely focused radiation beams to deliver high dose of radiation therapy in a few sessions to treat tumors. In this study, stereotactic radiosurgery will involve 3 radiation treatments.

After you finish radiosurgery with nivolumab, your doctor will continue to follow your condition for at least 100 days (with at least 8 months from completion of radiosurgery) and watch you for side effects. Your follow-up visits to the clinic or medical office will consist of routine physical exams and typically MRI scans.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision.

Risks

We want to make sure you know about a few key risks right now. We give you more information in the “What risks can I expect from taking part in this study?” section.

If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach for your brain tumor at shrinking or stabilizing your brain tumor.

There is also a risk that you could have side effects from the study approach. These side effects may be worse and may be different than you would get with the usual approach for your cancer.

Some of the most common side effects that the study doctors know about are:

- Tiredness
- Headache
- Nausea, vomiting, or diarrhea
- Fever, chills
- Rash
- As nivolumab is a drug that can activate your immune system, there can be rare and unpredicted immune-related reactions or even swelling around your tumor

There may be some risks that the study doctors do not yet know about.

Benefits

There is evidence from laboratory research using tumors implanted in mice that a combination of radiation with nivolumab may shrink or stabilize tumors for longer than each individual approach alone. There have also been some reports of patients with your type of brain tumor responding to nivolumab alone or radiosurgery alone. However, we do not know if the combination will be better or will help you live longer than the usual approach of radiosurgery alone. This study may help the study doctors learn things that may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop taking part in the study at any time.

If you decide to stop, let your study doctor know as soon as possible. It's important that you stop safely. If you stop, you can decide if you want to keep letting the study doctor know how you are doing.

Your study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes and the study is no longer in your best interest.
- New information becomes available and the study is no longer in your best interest.
- You do not follow the study rules.
- For women: You become pregnant while on the study.
- The study is stopped by the Institutional Review Board (IRB), Food and Drug Administration (FDA), or study sponsor (National Cancer Institute, NCI). The study sponsor is the organization who oversees the study.

It is important that you understand the information in the informed consent before making your decision. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask your study doctor or nurse.

What is the purpose of this study?

This study uses nivolumab which has already been approved by the FDA to treat other cancers. The purpose of this study is to see if the combination of nivolumab with radiosurgery will shrink or stabilize your type of recurrent brain tumor. There will be approximately 23 people taking part in this phase II portion of the study.

What are the study groups?

There are two parts in this study, a phase I portion and a phase II portion. You are participating in the phase II portion. In the previously completed phase I portion, we determined which combination of study drugs with radiosurgery was best tolerated by people with this type of brain tumor: radiosurgery with nivolumab (Treatment A) or radiosurgery with nivolumab and ipilimumab (Treatment B).

The combination that was best tolerated was radiosurgery with nivolumab (Treatment A), which has been selected for the phase II portion. Radiosurgery will take place every other day for Days 1, 3, and 5 (up to 3 sessions). Nivolumab will be given through a vein in your arm every 4 weeks for up to 13 doses.

See the study calendar at the end of this document for more information.

You will not be able to get additional doses of the study drug. This drug is not approved by the FDA for treatment of your disease.

Phase II – Treatment A

A group of 18-23 people: Radiosurgery (Days 1, 3, 5) and nivolumab (every 4 weeks for 12 months)

What exams, tests, and procedures are involved in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. If you join the study, you will have more exams, tests, and procedures to closely monitor your safety and health. Most of these are included in the usual care you would get even if you were not in a study.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study dosing, including preventing and managing side effects.

These exams, tests, and procedures to monitor your safety and health include:

- Thyroid testing done every 8 weeks

Some exams, tests, and procedures are a necessary part of the research study, but would not be included in usual care. Listed below are procedures that will be done for research purposes only.

You will need to have a blood sample for the study. Blood will be taken before you begin any study dosing, during Week 4, during Week 12, and if your disease returns. The blood will be used to for different types of research, including genetic research and research to characterize your immune response to the drugs. You and/or your study doctor will not get the results of this testing.

Your study doctor will need to use some of the tissue left over from your biopsy or surgery when you were diagnosed with your brain tumor. This sample is a required part of the study. It will be banked for future research. If your tumor returns and you have additional surgery, your study doctor will also request additional tissue that is removed from the surgery for future studies to understand how the tumor may be resisting the study drugs. You and/or your study doctor will not get the results of this testing.

A patient study calendar is attached at the end of this document. It shows how often these exams, tests, and procedures will be done.

What risks can I expect from taking part in this study?

General Risks

If you choose to take part in this study, there is a risk that the study approach may not be as good as the usual approach for your brain tumor at shrinking or stabilizing your brain tumor.

You also may have the following discomforts:

- Spend more time in the hospital or doctor’s office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The drugs used in this study could be very harmful to an unborn or newborn baby. There may be some risks that doctors do not yet know about. It is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 5 months (if you are a woman) or 7 months (if you are a man) after you have completed the study.

This study will use a sample of your tissue. Generally, your hospital will keep some of your tissue. This tissue may be used to help treat your brain tumor in the future. Because this study will need to use some of this tissue, there is a small risk that it could be used up.

Genetic Testing Risks

The genetic test used in this study will test your tumor and normal tissue for genetic changes. Changes found in your normal tissue may be passed down in families. For example, these genetic changes may be passed down to your children in the same way that eye and hair color are passed down.

Genetic tests of normal tissue can reveal information about you and also about your relatives. Your doctor will talk with you about what the tests results may mean for you and your family. He or she also may suggest you talk with a genetics counselor to learn more. You or your insurance plan would have to pay for visits to a genetic counselor.

Side Effect Risks

The drugs used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will test your blood and let you know if changes occur that may affect your health.

There is also a risk that you could have other side effects from the study drugs.

Here are important things to know about side effects:

1. The study doctors do not know who will or will not have side effects.
2. Some side effects may go away soon, some may last a long time, and some may never go away.
3. Some side effects may make it hard for you to have children.
4. Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

This study is looking at a combination of the usual radiosurgery used to treat this type of brain tumor plus one or two study drugs. This different combination of drugs and radiosurgery may increase your side effects or may cause new side effects.

Drug Risks

The tables below show the most common and most serious side effects doctors know about. Keep in mind that there might be other side effects doctors do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of Nivolumab
(Table Version Date: June 10, 2023)

Special precautions Side effects of Nivolumab may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when Nivolumab is used in combination with ipilimumab. **Call or see your healthcare provider right away if you develop any problems listed below or the symptoms get worse.**
COMMON, SOME MAY BE SERIOUS In 100 people receiving nivolumab, more than 20 and up to 100 may have:
• Tiredness

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving nivolumab, from 4 to 20 may have:
• Anemia which may require blood transfusion • Swelling and redness of the eye • Pain • Diarrhea, nausea • Dry mouth • Fever • Swelling and redness at the site of the medication injection • Bruising, bleeding • Pain or swelling of the joints • Loss of appetite • Reaction during or following a drug infusion which may cause fever, chills, rash Nivolumab may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to: • Lung problems (pneumonitis and pleural effusion). Symptoms may include: new or worsening cough, chest pain, shortness of breath. • Intestinal problems (colitis) that can rarely lead to tears or holes in your intestine. Signs and symptoms of colitis may include: diarrhea or increase in bowel movements, blood in your stools or dark, tarry, sticky stools, severe belly pain or tenderness. • Skin: itching; rash, blisters including inside the mouth; loss of skin pigment • Liver problems (hepatitis) which can cause liver failure. Signs and symptoms of hepatitis may include: yellowing of your skin or the whites of your eyes, severe nausea or vomiting; drowsiness; pain in the right upper belly • Hormone gland problems (especially the thyroid, pituitary and adrenal glands, and pancreas). Signs and symptoms may include: headaches that will not go away or

unusual headaches, extreme tiredness or changes in mood or behavior; decreased sex drive; weight loss or weight gain; excessive thirst or urine; dizziness or fainting.

RARE, AND SERIOUS

In 100 people receiving nivolumab, 3 or fewer may have:

- Swelling of arms and legs which may cause a feeling of heaviness and tightness
- Dry eyes
- Sores in the mouth which may cause difficulty swallowing
- A syndrome starting with flu-like symptoms and followed by swelling, tenderness which may cause flu-like symptoms, blurred vision, ringing in the ears, changes in hair or hair loss
- Swelling of the bowels

Nivolumab may cause your immune system to attack normal organs and cause side effects in many parts of the body. These problems may include but are not limited to:

- Visual disturbances which may cause double vision, blurred vision, or loss of vision with a chance of blindness
- A condition with high blood sugar which leads to tiredness, frequent urination, excessive thirst, headache, nausea and vomiting, and can result in coma
- Kidney problems, including nephritis and kidney failure requiring dialysis. Signs of kidney problems may include: decrease in the amount of urine, blood in your urine, ankle swelling.
- Heart problems including swelling and heart failure. Symptoms and signs of heart problem may include: Shortness of breath, swelling of the ankle and body.
- Problem of the muscle, including swelling, which can cause muscle pain and severe muscle weakness sometimes with dark urine
- Swelling of the brain (meningitis/encephalitis) which may cause: headache, stiff neck confusion, sleepiness, seizures or injury to the brain which may cause headache, seizure, blindness (also known as Reversible Posterior Leukoencephalopathy Syndrome)
- Problem of the nerves that can cause paralysis. Signs and symptoms may include: numbness, tingling of hands and feet; weakness of the arms, legs and facial muscle movement
- Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat
- Complications associated with stem cell transplant using donor stem cells (allogeneic stem cell transplant). These complications are caused by attack of donor cells on the host organs (inducing liver, skin and gut damage), and can lead to death. If you are considering an allogeneic stem transplant after participating in this study, please tell your doctor that you have received Nivolumab therapy, since the risk and severity of transplant-associated complications may be increased.

Additional Drug Risks

Rarely, there are problems getting enough supplies of the study drug. If that happens, your doctor will talk with you about your options.

Possible Side Effects of Stereotactic Radiosurgery

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 20 to 100 may have:
• Reddening, tanning, or peeling of the skin • Mild pain • Hair loss • Tiredness • Headache • Nausea, or vomiting

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, 4 to 20 may have:
• Thickening and numbness of the skin • Sores or ulcers on the skin or near the tumor location • Permanent hair loss • Seizure • Radiation-related inflammation or sometimes called radiation necrosis

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Eye damage, resulting in worsening of vision or possible blindness • Weakness or numbness in your face, arms, or legs • Progressive thickening and hardening of the walls of medium-sized and large arteries • Cancer caused by the radiation, though this is thought to be very unlikely for radiosurgery

What are my responsibilities in this study?

If you choose to take part in this study you will need to:

- Keep your study appointments.
- Tell your doctor about:
    - all medications and supplements you are taking
    - any side effects
    - any doctors' visits or hospital stays outside of this study
    - if you have been or are currently in another research study.

For women: Do not get pregnant or breastfeed while taking part in this study. Tell your study doctor right away if you think that you have become pregnant during the study or within 5 months after your last dose of study drug. **For men:** Do not father a baby while taking part in

this study. Tell your study doctor right away if you think that your partner has become pregnant during the study or within 7 months after your last dose of study drug.

What are the costs of taking part in this study?

You and/or your insurance plan will need to pay for the costs of medical care you get as part of the study, just as you would if you were getting the usual care for your cancer. This includes:

- the costs of tests, exams, procedures, and drugs that you get during the study to monitor your safety, and prevent and treat side effects; these are tests and procedures that are part of typical care if not in a study.
- the costs of getting the nivolumab ready and giving it to you.
- the cost of radiosurgery
- your insurance co-pays and deductibles.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it doesn't pay for if you take part in this clinical trial. Also, find out if you need approval from your plan before you can take part in the study.

Ask your doctor or nurse for help finding the right person to talk to if you are unsure which costs will be billed to you or your insurance provider.

You and/or your insurance provider will not have to pay for exams, tests, and procedures done for research purposes only or that are covered by the study. These include:

- The research blood draws throughout the study unless they are done at the time of your standard of care blood draws

You or your insurance provider will not have to pay for the nivolumab while you take part in this study.

Taking part in this study may mean that you need to make more visits to the clinic or hospital than if you were getting the usual approach to treat your cancer. You may:

- Have more travel costs.
- Need to take more time off work.
- Have other additional personal costs.

You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What happens if I am injured because I took part in this study?

If you are injured as a result of taking part in this study and need medical treatment, please talk with your study doctor right away about your treatment options. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for a study-

related injury. Ask them if they will pay. If you do not have insurance, then you would need to pay for these medical costs.

If you feel this injury was caused by medical error on the part of the study doctors or others involved in the study, you have the legal right to seek payment, even though you are in a study. Agreeing to take part in this study does not mean you give up these rights.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Some of your health information, such as your response to cancer treatment, results of study tests, and medicines you took, will be kept by the study sponsor in a central research database. However, your name and contact information will not be put in the database. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

There are organizations that may look at your study records. Your health information in the research database also may be shared with these organizations. They must keep your information private, unless required by law to give it to another group.

Some of these organizations are:

- The study sponsor and any company supporting the study now or in the future.
- The IRB, which is a group of people who review the research with the goal of protecting the people who take part in the study.
- The FDA and the groups it works with to review research.
- The NCI and the groups it works with to review research.
- The NCI's National Clinical Trials Network and the groups it works with to conduct research

Your study records also will be stored for future use. However, your name and other personal information will not be used. Some types of future research may include looking at your records and those of other patients to see who had side effects across many studies or comparing new study data with older study data. However, we don't know what research may be done in the future using your information. This means that:

- You will not be asked if you agree to take part in the specific future research studies using your health information.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your information.

There are laws that protect your genetic information. However, there is a risk that someone could get access to your genetic information and identify you by name. In some cases, employers could use your genetic information to decide whether to hire or fire you. The study doctors believe the risk of this happening is very small. However, the risk may increase in the future as people find new ways of tracing information. For more information about the laws that protect you, ask your study doctor.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor (*insert name of study doctor[s]*) at (*insert telephone number, and email address if appropriate*).

For questions about your rights while in this study, call the (*insert name of organization or center*) Institutional Review Board at (*insert telephone number*).

^Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here. ^

Sample collections for known laboratory studies and/or storage for possible future studies

Researchers are trying to learn more about cancer and other health problems using blood and tissue samples from people who take part in clinical trials. By studying these samples, researchers hope to find new ways to prevent, detect, treat, or cure diseases.

Some of these studies may involve analysis of genes, called genomic sequencing, to look at how genes affect a person's response to treatment. Genes carry information about traits that are found in you and your family. Examples of traits are the color of your eyes, having curly or straight hair, and certain health conditions that are passed down in families. Some of these studies may involve looking at different types of immune cells in the blood, called immunophenotyping. Some of the studies may lead to new products, such as drugs or tests for diseases. In this study, researchers will do genomic sequencing of your tumor and blood samples as well as immunophenotyping of your blood samples. These research may help us to understand your response to treatment.

Any of your tumor tissue or blood samples left over from the genomic sequencing and immunophenotyping will be stored for additional future studies. Storing samples for future studies is called "biobanking." The biobank is being run by the ETCTN Biorepository and is supported by the NCI. Also, any health-related information, such as your response to cancer treatment, results of study tests, and medicines you took, will be stored for future use. Your genomic sequence will also be stored in a secure NIH database for future use. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.

Unknown future studies

We do not know what other additional research may be done in the future using your tumor tissue and blood samples. This means that:

- You will not be asked if you agree to take part in the future research studies.
- You and your study doctor will not be told when or what type of research will be done.
- You will not get reports or other information about any research that is done using your samples.

What is involved in this sample collection?

If you agree to take part, here is what will happen next:

1. Before dosing, about 3 tablespoons of blood will be collected from a vein in your arm and will be sent to the biobank. A sample from the tissue that was collected at the time of your previous surgery will be sent to the biobank. If you require surgery in the future for recurrent tumor, a sample of tissue and 3 tablespoons of blood will be collected at the time of your surgery and will be sent to the biobank.
2. Your samples will be stored in the biobank. There is no limit on the length of time we will keep your samples and research information. The samples will be kept until they are used for research or destroyed.
3. Researchers can only get samples from the biobank after their research has been approved by experts. Researchers will not be given your name or contact information.
4. Some of your genetic and health information may be placed in central databases for researchers to use. The databases will not include your name or contact information.

What are the risks in this sample collection?

- The most common risks related to drawing blood from your arm are brief pain and maybe a bruise.
- Generally, hospitals will keep some of your tissue. This tissue may be used to help treat your cancer in the future. There is a small risk that when this tissue sample is submitted to the biobank for this optional sample collection, your tissue could be used up.
- Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. Researchers believe the chance that someone could access and misuse your information is

very small. However, the risk may increase in the future as people find new ways of tracing information.

- In some cases, this information could be used to make it harder for you to get or keep a job and get or keep health insurance. There are laws against the misuse of genetic information, but they may not give full protection. For more information about the laws that protect you, ask your study doctor or visit: https://www.genome.gov/10002328/

How will information about me be kept private?

Your privacy is very important to the study researchers and biobank. They will make every effort to protect it. Here are just a few of the steps they will take:

1. They will remove identifiers, such as your initials, from your sample and information. They will replace them with a code number. There will be a master list linking the code numbers to names, but they will keep it separate from the samples and information.
2. Researchers who study your sample and information will not know who you are. They also must agree that they will not try to find out who you are.
3. Your personal information will not be given to anyone unless is required by law
4. If research results are published, your name and other personal information will not be used.

What are the benefits to taking part in this sample collection?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments to this sample collection?

There are no costs to you or your insurance. You will not be paid for taking part in this study. The research may lead to new tests, drugs, or other products for sale. If it does, you will not get any payment.

What if I change my mind about this sample collection?

If you decide you no longer want your samples to be used, you can call the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial*), who will let the biobank know. Then, any sample that remains in the biobank will be destroyed or returned to your study doctor. This will not apply to any samples or related health information that have already been given to or used by researchers.

What if I have questions about this sample collection?

If you have questions about the use of your samples for research, contact the study doctor, (*insert name of study doctor for main trial*), at (*insert telephone number of study doctor for main trial*).

Please circle your answer below to show if you would or would not like to take part in each study:

Samples for unknown future studies:

I agree that my samples and related health information may be kept in a biobank for use in future health research.

YES NO

Contact for Future Research

I agree that my study doctor, or someone on the study team, may contact me or my doctor to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about sample research studies.

My signature agreeing to take part in the study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed and dated copy of this form. I agree to take part in the main study. I also agree to take part in any additional studies where I circled "yes".

Participant's signature

Date of signature

Signature of person(s) conducting the informed consent discussion

Date of signature

Study Calendar for People Receiving Radiosurgery with Nivolumab

	Screening	Baseline	Every 4 weeks	Week 4	Week 12	Every 12 weeks	If your tumor returns	Safety Follow-up
Physical exam	X		X					
Routine blood tests	X		X					
Thyroid testing	X		Every 8 weeks					
Routine pregnancy test if you are a woman of childbearing potential	X							
Routine brain MRI	X				X	X		
Nivolumab			X					
Radiosurgery			Days 1, 3, and 5 only					
Blood for research testing		X		X	X		X	
Collection of leftover tissue from your diagnosis for research testing		X						
Collection of tissue from surgery (if you have it) for research testing							X	
Review of symptoms and side effects		During treatment and for at least 100 days after your last day of treatment						